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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,674	04/02/2002	Shuwen Lee	2896-4006	6925

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EXAMINER
TRAVERS, RUSSELL S

ART UNIT	PAPER NUMBER
1617	4

DATE MAILED: 07/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/089,674	Applicant(s) Lee
	Examiner R.S. Travers J.D., Ph.D.	Art Unit 1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Nov 5, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-4* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

The amendment filed April 2, 2002 has been received and entered into the file.

The amendment filed April 2, 2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Orotic acid, page 15, line 17; and the case studies inserted beginning at page 23, line 2. Neither the term Orotic acid, nor those case studies added at page 23 are supported by the specification as filed.

Applicant is required to cancel the new matter in the reply to this Office Action.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-4 are rejected under 35 U.S.C. § 103 as being unpatentable over Chinese Patent no. 1129113 (CN 113), Weische ret al, Shenfeld, Pauza et al, Haines et al and Asanaka et al, of record or newly cited.

Chinese Patent no. 1129113 (CN 113) teaches methionine, silybin, vitamin B3, vitamin C, Vitamin B6, folic acid, vitamin B12, and thioctic acid, respectively (see claim 1, or table 1) as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. These medicaments are taught as old and well known as useful for treating viral infections, specifically HIV infections. Weische ret al teach vitamin A, vitamin B1, vitamin B6, vitamin B12, and vitamin C as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. These medicaments are taught as old and well known as useful for treating viral infections, specifically HIV infections. Shenfeld teaches Calcium glycerophosphate as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. This medicament is taught as old and well known as useful for treating viral infections, specifically HIV infections. Pauza et al teach vitamin D as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. This medicament is taught as old and well known as useful for treating viral infections, specifically HIV infections. Haines et al and Asanaka et al vitamin B5 as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. All mediciments herin claimed are taught individually, or

concomitantly as useful for treating viral etiological agents specifically HIV. Claims 1-4, and the primary references, differ as to:

1) the concomitant employment of these medicaments, and

2) administration levels of the medicaments.

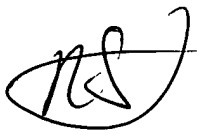
It is generally considered prima facie obvious to combine two compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of two conventional anti-viral agents. It would follow that the recited claims define prima facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

Claims 1-4 specifically require pharmaceutical compositions containing discrete medicament levels . Examiner cited prior art teaches medicaments at levels providing therapeutic effects against the etiological agent herein envisioned. These medicament levels are set forth in Chinese Patent no. 1129113 (CN 113) at figure 1 and in claim 1; by Weischer et al at page 4, lines 9-10; by Shenfeld at page 7; by Pauza et al at page 28, by Haines et al an column 7 and by Asanaka et al in the abstract. The skilled artisan would have seen conventional compositions, and the administration of these compositions in conventional manners as residing in the skilled artisan purview.

Determining the active ingredient dosage level required to effect optimal therapeutic benefit is well within the Skilled Artisan's purview, and the benefits of achieving such maximization obvious, to said skilled artisan. The claims merely recite the obvious employment of old and well known active ingredients, carriers and excipients. Thus, the only issue presented in the instant application is the obviousness of the claimed antiviral compositions.

No claims are allowed.

Any inquiry concerning this communication should be directed to Russell Travers at telephone number (703) 308-4603.



Russell Travers J.D., Ph.D.
Primary Examiner
Art Unit 1617